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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,713	01/08/2002	George Kindness		2565

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EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/040,713	KINDNESS ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 11-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-30 are pending.

Election/ Restriction

2. Applicant's election of claims 6-10 in Paper of 13 August 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Accordingly, Claims 1-5 and 11-30 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited supra be canceled in response to this Office action to expedite prosecution.

Information Disclosure Statement

4. Applicants' Information Disclosure (i.e., IDS) filed February 14, 2002 ~~as paper number 2~~ has been made of record and considered.

Priority

5 Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Claim Rejections - 35 U.S.C. § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> ***The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.***

7. Claims 6-10 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with those claims. The claims are directed to a method to treat vascular insufficiency, wherein a composition comprising cystine, EDTA, selenium, vitamin C, vitamin E and zinc mixed with pharmaceutical excipient is administered.

From the record of the present written disclosure, the specification, while enabling for obtaining a pharmaceutical composition comprising a mixture of a pharmaceutical excipient with chemicals described *supra* does not reasonably teach treatment of vascular insufficiency because applicants have not demonstrated treatment of any disease commonly considered to be vascular insufficiency (see, e.g., Merck Manual, Page 1599-1601). Furthermore, the examples in the specification demonstrate a method to measure platelet aggregation (See for e.g., specification Page 15, Line 10 to Page 17, Line 29) and normal/baseline values for a variety of biochemical parameters (Tables I to VIIIB) without showing any results on the effects of those parameters post- administering composition in the claimed method or how values presented for those parameters are related to vascular efficiency. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to extrapolate the claimed invention method to treat either vascular insufficiency or any or all of the vascular insufficiency related disease. In the absence of demonstrated evidence of record that the said method achieves what is being claimed in the instant invention, the claimed invention is not considered enabled.

Furthermore, from the record of the present written disclosure, claims 6-10 are also non-enabling for the scope of the claims with regard to assessing either glutathione or platelet aggregation, because said method has not been claimed in the claims. Applicants have merely demonstrated a method of measuring those parameters but results presented do not show any effect of the method of claimed invention wherein composition in the claimed invention has been administered to a patient in need of claimed treatment method.

An ordinary artisan would not be able to practice the invention because in absence of a teaching about the results obtained from the method of claimed invention, it will be difficult to correlate the results on platelet aggregation or glutathione concentration, especially when said tests are routinely not performed in most of Clinical Laboratories (See Specification, Pages 12-13, Line bridging pages 12 and 13). Undue experimentation will be required to obtain a pattern of these parameters (i.e., glutathione concentration and platelet aggregation) in normal, diseased (i.e., patients suffering from vascular insufficiency, especially in absence of a definition or understanding of which vascular insufficiency related disease is being evaluated), or treated patients due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

8. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 6-10 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The recitation, "vascular insufficiency" in claim 6 renders that claim unclear and therefore indefinite because the term does not clearly define the metes and bounds of the claimed subject matter. Applicant is requested to define if this term means any or all diseases related to cardiovascular system.

All other claims depend directly from the rejected claim and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 103

10. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § *102*(f) or (g) prior art under 35 U.S.C.§ 103(a).

12. Claims 6-10 are rejected under 35 U.S.C. § 103 (a) as obvious over Howard et al. (WO/9500130) in view of Jacobson et al. (US Patent 6,337,065).

Howard et al. teach a method to treat coronary heart disease or cardiovascular disease by administering to a subject suffering from said disease a therapeutic/ pharmaceutical composition comprising antioxidants, wherein said composition is comprised of Vitamin C, Vitamin E, selenium and zinc (Page 30, Line 19 to Page 31, Line 1 and Page 29, Lines22-23). This antioxidant composition intrinsically comprises a pharmaceutically acceptable carrier because it is a pharmaceutical composition. Howard et al. do not teach a composition further comprising cystine and EDTA.

Jacobson et al. teach a DNA repair method by administering an antioxidant composition comprising cystine, EDTA, selenium, zinc and vitamins C and E (Column 14, Lines 12-55)

An artisan of ordinary skill would be motivated to modify the teachings of Howard et al. with those of Jacobson et al. because each one of the cited prior art references teaches a method to administer a composition comprising antioxidants, wherein said compositions comprise overlapping ingredients (i.e., selenium, zinc and Vitamins C and E) to treat a subject suffering from a disease. Jacobson et al. remedy the deficiency of cystine and EDTA in the composition that Howard et al. teach.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine teachings from Howard et al. and Jacobson et al. to obtain a method to treat iseases (i.e., coronary heart disease or cardiovascular disease) that are treatable with a composition comprising antioxidants because both prior art references teach administering a pharmaceutical antioxidant composition to a subject in need thereof.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

13. No Claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703) 605-1196

October 28, 2003

Jon P. Weber, Ph.D.
Primary Examiner